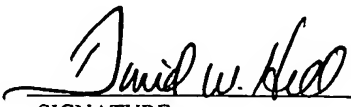


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|---|--|---|
| FORM PTO-1390 • U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE REV. 2/01T | | CUSTOMER NO. 22,852 ATTORNEY'S DOCKET NUMBER 09707.0001 |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | U.S. APPLICATION NO.: 10/519,162 (If known, see 37CFR1.5) |
| | | |
| INTERNATIONAL APPLICATION NO. PCT/JP2003/008134 | INTERNATIONAL FILING DATE June 26, 2003 | PRIORITY DATE CLAIMED June 26, 2002 |
| TITLE OF INVENTION DRUG COMPOSITION CONTAINING NF-κB INHIBITOR | | |
| APPLICANT(S) FOR DO/EO/US 1) Kazuo UMEZAWA; 2) Yohko KAWAI; 3) Ryouichi HORIE; 4) Toshiki WATANABE; 5) Masakazu TOI; 6) Gaku MATSUMOTO; 7) Yutaka Horiguchi; 8) Jun NAKASHIMA | | |
| Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| 1. | <input type="checkbox"/> | This is a FIRST submission of items concerning a filing under 35 U.S.C 371. |
| 2. | <input checked="" type="checkbox"/> | This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. |
| 3. | <input type="checkbox"/> | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. |
| 4. | <input type="checkbox"/> | The US has been elected by the expiration of 19 months from the priority date (Article 31). |
| 5. | <input type="checkbox"/> | A copy of the International Application as filed (35 U.S.C. 371 (c)(2)). |
| | a. <input type="checkbox"/> | is attached hereto (required only if not communicated by the International Bureau. |
| | b. <input type="checkbox"/> | has been communicated by the International Bureau. |
| | c. <input type="checkbox"/> | is not required, as the application was filed with the United States Receiving Office (RO/US). |
| 6. | <input type="checkbox"/> | An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)). |
| | a. <input type="checkbox"/> | is attached hereto. |
| | b. <input type="checkbox"/> | has been previously submitted under 35 U.S.C. 154 (d)(4). |
| 7. | <input type="checkbox"/> | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)). |
| | a. <input type="checkbox"/> | are attached hereto (required only if not communicated by the International Bureau). |
| | b. <input type="checkbox"/> | have been communicated by the International Bureau. |
| | c. <input type="checkbox"/> | have not been made; however, the time limit for making such amendments has NOT expired. |
| | d. <input type="checkbox"/> | have not been made and will not be made. |
| 8. | <input type="checkbox"/> | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). |
| 9. | <input type="checkbox"/> | An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). |
| 10. | <input type="checkbox"/> | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). |
| Items 11 to 20 below concern document(s) or information included: | | |
| 11. | <input checked="" type="checkbox"/> | Information Disclosure Statement under 37 CFR 1.97 and 1.98 |
| 12. | <input type="checkbox"/> | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. |
| 13. | <input type="checkbox"/> | A FIRST preliminary amendment. |
| 14. | <input type="checkbox"/> | A SECOND or SUBSEQUENT preliminary amendment. |
| 15. | <input type="checkbox"/> | A Substitute specification. |
| 16. | <input type="checkbox"/> | A change of power of attorney and/or address letter. |
| 17. | <input type="checkbox"/> | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. |
| 18. | <input type="checkbox"/> | A second copy of the published international application under 35 U.S.C. 154 (d)(4). |
| 19. | <input type="checkbox"/> | A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4). |
| 20. | <input checked="" type="checkbox"/> | Other items or information: |
| | a. <input checked="" type="checkbox"/> | Copies of documents and translations cited on PTO/SB/08 |
| | b. <input type="checkbox"/> | |
| | c. <input type="checkbox"/> | |

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|---|--------------|---|------------|---|----|--|--|
| U.S. APPLICATION NO. (If known, see 37CFR 1.5) 10/519,162 | | INTERNATIONAL APPLICATION NO. PCT/JP2003/008134 | | ATTORNEY'S DOCKET NUMBER 09707.0001 | | | |
| 21. <input type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): \$300.00 National Stage Search Fee.....\$500.00 National Stage Examination Fee.....\$200.00 <div style="text-align: right;">ENTER APPROPRIATE BASIC FEE AMOUNT = \$</div> | | | | CALCULATIONS PTO USE ONLY | | | |
| | | | | | | | |
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| | | | | | | | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)). | | | | \$ | | | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | | | |
| Total Claims | = | | x \$50.00 | \$ | | | |
| Independent Claims | = | | x \$200.00 | \$ | | | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | +\$360.00 | \$ | | | |
| TOTAL OF THE ABOVE CALCULATIONS = | | | | \$ | | | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. | | | | \$ | | | |
| SUBTOTAL = | | | | \$ | | | |
| Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest priority date (37 CFR 1.492(f)). | | | | \$ | | | |
| TOTAL NATIONAL FEE = | | | | | | | |
| Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property. | | | | \$ | | | |
| TOTAL FEES ENCLOSED = | | | | \$ | | | |
| | | | | Amount to be refunded: | \$ | | |
| | | | | charged: | \$ | | |
| a. <input type="checkbox"/> A check in the amount of \$ _ to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06/0916</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status. | | | | | | | |
| SEND ALL CORRESPONDENCE TO: Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001-4413 | | | | | | | |
| DATED: June <u>1</u> , 2006 | | | | <div style="text-align: center;">  SIGNATURE David W. Hill, Reg. No. 28,220 NAME/REGISTRATION NO. </div> | | | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|---|----------------------------|
| In re Application of: Kazuo UMEZAWA et al. |) | |
| |) | |
| Application No.: 10/519,162 |) | |
| |) | Group Art Unit: Not Yet |
| Filed: December 23, 2004 |) | Assigned |
| |) | |
| National Stage of International Application No. |) | Examiner: Not Yet Assigned |
| PCT/JP2003/008134 under 35 U.S.C. 371 |) | |
| |) | |
| For: DRUG COMPOSITION CONTAINING NF- |) | |
| κB INHIBITOR |) | |

MAIL STOP PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§1.56 and 1.97(b), Applicants bring to the Examiner's attention the documents listed on attached Form PTO/SB/08. With the exception of the U.S. patent, a copy of each listed document is attached. Applicants respectfully request that the Examiner consider the documents listed on attached Form PTO/SB/08 and indicate that they were considered by making an appropriate notation on this form.

To the undersigned's knowledge, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

The following are listed on the accompanying PTO/SB/08 and are in a non-English language:

1. WO 01/12588. An English-language abstract of the document is found on the first page. In addition, it is believed that U.S. Patent No. 6,566,394 is an English language equivalent of this document.

2. First Office Action issued by Chinese Patent Office in counterpart Chinese application no. 03814974.5 on April 7, 2006. An English translation is provided.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 7, 2006

By: David W. Hill
David W. Hill
Reg. No. 28,220

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|--|---|----|-----------------------------|-------------------------------|------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | Complete if Known | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | <i>Application Number</i> | 10/519,162 | |
| | | | <i>Filing Date</i> | December 23, 2004 | |
| | | | <i>First Named Inventor</i> | Kazuo UMEZAWA | |
| | | | <i>Art Unit</i> | Not Yet Assigned | |
| | | | <i>Examiner Name</i> | Not Yet Assigned | |
| Sheet | 1 | of | 1 | <i>Attorney Docket Number</i> | 09707.0001 |

| U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS | | | | | |
|---|--------------------------|---|--|--|---|
| Examiner Initials | Cite No. ¹ | Document Number | Issue or Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² <i>(if known)</i> | | | |
| | | 6,566,394 | 05-20-2003 | Takeuchi et al. | |
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Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|--|--------------------------------|--|--|--------------------------|
| Examiner Initials | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation ⁶ |
| | | Country Code ³ Number ⁴ Kind Code ⁵ <i>(if known)</i> | | | | |
| | | WO 01/12588 | 02-22-2001 | Merican Corporation | | Abstract |
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| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|---|--------------------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation ⁶ |
| | | Copy of First Office Action issued by Chinese Patent Office in counterpart Chinese application no. 03814974.5 on April 7, 2006. | yes |
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|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.